**510(k) summary**

21 CFR 807.92

Date: July 25, 2003
Official Contact: Winston Greer, Director, QA & RA
Manufacturer: BioHorizons Implant Systems, Inc.
One Perimeter Park South
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Birmingham, AL 35243
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Proprietary Name

The Maestro System™ Maximus 3.0mm Diameter Implant

Common Name

Screw-type Dental Implant

Classification Name

Endosseous implants, surgical components, and prosthetic attachments

Predicate Devices

Predicate devices are:

1. The Maestro System™, a screw-type endosseous implant manufactured and distributed by BioHorizons Implant Systems, Inc. Authorization to legally market the predicate implant system has been documented under 510(k) numbers K960026, K964330, K972313, K010458, K020133, K020645, K022795 and K030463.
2. The Altiva Natural Tooth Replacement (NTR) System 3.3mm diameter implant, a one-piece screw-type endosseous implant for long-term applications manufactured and distributed by Altiva Corporation and cleared for market under 510(k) number K992512.
3. The Sendax Mini Dental Implant (MDI) 1.8mm diameter implant, a one-piece screw-type endosseous implant for transitional and long-term applications manufactured and distributed by Imtec Corporation and cleared for market under 510(k) numbers K972351, K990983 and K023067.

Device Description

The BioHorizons Maestro System 3.0mm diameter dental implant is a machined titanium, screw-form implant supplied in lengths of 12mm, 15mm and 18mm. Implant raw material is titanium alloy as specified in ASTM F 136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications.*

The device is further processed by treating the surface with resorbable blast media (RBM). The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of $10^{-6}$, validated in compliance to ANSI/AAMI/ISO 11137, *Sterilization of healthcare products - Requirements for validation and routine control - Radiation Sterilization.*

The Maestro System™ 3.0mm Diameter Implant is a comprehensive system containing implants and surgical components. The BioHorizons 3.0mm diameter implant may be used: (1) as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored with a temporary prosthesis that is not in functional occlusion; (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors. The implants may be restored after a period of time or placed in immediate function; (3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.

All BioHorizons implants referenced in this submission are 3.0mm in diameter with D3 thread form and surface treated using resorbable blast media (hydroxylapatite conforming to ASTM F 1185, *Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants*). The following table provides a summary of the proposed implant catalog item or reference numbers by length.

| Lengths (mm) | Catalog REF Numbers |
|---|---|
| 12 | 3012D3 |
| 15 | 3015D3 |
| 18 | 3018D3 |

Intended Use

The BioHorizons 3.0mm diameter implant may be used:

(1) as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

(2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors. The implants may be restored after a period of time or placed in immediate function.

(3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.

Technological Characteristics

The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices. All materials, suppliers, processing, packaging and sterilization methods remain the same as for the predicate Maestro System devices. The BioHorizons 3.0mm diameter implants are substantially equivalent to all features of the predicate devices which could affect safety or effectiveness because of the similarities in design, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2003

Mr. Weston D. Greer
Director Assurance & Regulatory Affairs
Biohorizons Implant System, Incorporated
One Perimeter Park South
Suite 230 South
Birmingham, Alabama 35243

Re: K032351
Trade/Device Name: Biohorizons the Maestro System™ 3.0mm Diameter Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: July 25, 2003
Received: July 31, 2003

Dear Mr. Greer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cucente for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K032351

Device Name: BioHorizons The Maestro System™ 3.0mm Diameter Implant

Indications for Use:

The BioHorizons Maestro System 3.0 mm Diameter Implant may be used
(1) as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.
(2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors. The implants may be restored after a period of time or placed in immediate function.
(3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032351

Prescription Use _____ OR Over-the-Counter Use _____
(per 21 CFR 801.109)